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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,852	09/22/2000	Per Johan Lundberg	1103326-0686	1116

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EXAMINER
DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/646,852	LUNDBERG ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-20 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Applicant's amendment, filed on June 19, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (EP 0237200) in view of Okada et al. (JP402237918) or Preston et al. (U.S. Patent 5,776,489).

Makino et al. discloses pharmaceutical compositions of benzimidazole derivatives, including omeprazole, said compositions prepared by mixing the drug with basic inorganic salts and additives, including vehicles such as sucrose (an osmotic agent) and cellulose, binders such as hydroxypropyl cellulose and PVP, and lubricants, such as talc (See p. 8, lines 14-23). Makino et al. teaches that the mixture can be made up into dosage forms, such as tablets and capsules and the tablets may be coated by known methods to mask the taste or provide the dosage forms with sustained release properties, and includes ethyl cellulose and cellulose acetate among the coating agents used in the invention (See p. 8, lines 34-41). Makino et al. contemplates both enteric and sustained release polymer coatings, however, one of ordinary skill in the art interested in providing the formulations of the invention with sustained release properties, would have been

guided by the teachings of Makino et al. to select water-insoluble polymers, such as ethyl cellulose, rather than enteric polymers, to provide the dosage forms with said release properties. Makino et al. does not specify the amount of each additive in the formulations of the invention, however, one of ordinary skill in the art would have been able to determine the optimal concentration of each additive by routine experimentation. Makino et al. is deficient in the fact, that it does not specifically teach that the coating may comprise a modifying agent.

Okada et al. provides a long acting coating film comprising ethyl cellulose and talc for sustained release formulations.

Preston et al. provides granules coated with film forming polymers and includes Surelease, a commercial coating comprising ethyl cellulose and fumed silica, among the coatings useful in the invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Makino et al. to device sustained release dosage forms of omeprazole, and include in the coating a modifying agent, as taught by Okada et al. or Preston et al., to improve the response to changes in environment pH . The expected result would have been a successful dosage form of omeprazole and successful methods of manufacturing and administering said dosage form . Because of the teachings of Makino et al., that sustained release pharmaceutical compositions of omeprazole exhibit excellent gastric anti-secretory and anti-ulcer activities, one of ordinary skill in the art would have a reasonable expectation that the

compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

3. Applicant's arguments filed on June 19, 2003, have been fully considered but they are not persuasive.

4. Applicant argues that Makino et al. is limited to dosage forms having enteric or sustained release properties, whereas the claimed invention has neither enteric nor sustained release properties, and the dosage form of the claimed invention is not enteric coated. Applicant relies on the definition provided by the article published in australianprescriber.com for the teachings that delayed release products are not sustained release. In response to said argument, it is noted that the article Applicant relies on teaches that "Delayed-release products are modified-release, but by definition are not extended-release. They involve the release of discrete amount(s) of drug some time after drug administration, e.g. enteric-coated products, and exhibit a lag time during which little or no absorption occurs". Thus, the article defines delayed-release products as enteric-coated products. Applicant, instead, argues that the claimed dosage form is not enteric coated. Additionally, it is noted that Makino et al. includes ethyl cellulose, which is a water-insoluble polymer, among the coating agents used in the invention. Thus the prior art disclosure of the same coated compositions provides the same release effects claimed by Applicant.

5. In response to Applicant's argument, regarding the delayed release profile of the claimed invention, it is noted that the instant claims do not include the limitations shown in Example 4 of the specification and cited by Applicant. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. In response to Applicant's argument, that at the time the claimed invention was made it was the art-recognized practice to apply an enteric coating layer to oral dosage forms of omeprazole, it is recommended that Applicant submits a declaration supported by scientific data to show that it was unconceivable to prepare an oral formulation of omeprazole without an enteric coating.

Conclusion

7. Claims 1, 3-20 and 23-27 stand rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDNB3

September 3, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600